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EXAMINER
MARSCHEL, A

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11/15/90 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ ~~days~~ from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-15 are pending in the application.
   Of the above, claims 8-15 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-7 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Applicant's election of Group I (claims 1-7) in Paper No. 8, filed 11/15/90, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

A preliminary amendment received 4/10/89 was not entered because it was not signed. A signed version of this same preliminary amendment was filed 1/16/90. Unfortunately, when an attempt was made to enter the signed preliminary amendment a vast number of errors was encountered which prevented entry of the majority of this preliminary amendment. For example, on page 3, line 9, of said preliminary amendment the insertion of a citation in place of "(2, 3)" could not be done because there is no "(2, 3)" on line 22 of page 2 in the specification. At the next insertion to replace "(4)", there is no "(4)" on page 2, line 26, of the specification. Then there is a replacement for "(23)" which is to be done on page 2, line 52, and page 39, line 43. The Examiner wishes to note that none of the specification pages have as many as either 52 or 43 lines. It is clear that this preliminary amendment cannot be entered due to the massive errors therein. The Examiner requests that applicants clarify what is to be done with this amendment.

The instant application contains numerous minor errors that are either typographical errors, misspellings, or scientific omissions/errors. Although these appear to be minor, they introduce unclarities that may weaken the clear and concise description of the invention disclosed therein. The Examiner requests that applicant(s) review the disclosure and amend these minor aspects to remove the errors without adding new matter. Some examples of these minor errors are as follows:

On page 9, line 13, the word "call" appears to be of the wrong verb tense and thus awkward.

On page 9, line 16, the word "disclose" appears to be of the wrong verb tense and thus awkward.

On page 45, line 25, the word "to" appears to be misspelled.

On page 53, line 8, the word "does" appears to be misspelled.

The use of the trademark TRITON X-100 (page 31, line 23, and elsewhere) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

On page 15, line 13, Figure 4 is cited as depicting "hydrophobicity" whereas Figure 4 shows a graph labeled with "hydropathicity". It is unclear as to why two different terms are used and what parameter is being shown in Figure 4.

It is unclear and confusing as to why the drawings contain Figure legends since such legend disclosures are to be given in the specification as descriptions of the drawings. The drawings

seem to be laid out as Figures rather than drawings as per proper patent disclosure procedures.

The disclosure of Figures 2 and 3 conflict since Figure 2 indicates that the termini of the T11 sequence are EcoR I sites whereas the termini of the Figure 3 sequence are not EcoR I sites. Additionally, Figure 2 shows a section of T11 containing subsections labeled "a", "b", and "c". This is confusing since there are identically labeled subsections in Figure 3 in the sequence lines starting with 2641 through 3001. What is the relationship between these sections?

On page 18, lines 19-23, the Figure 3 sequence is cited as being "for the TR4 cDNA clone" whereas the Figure 3 legend states that the sequence is T11. What is the sequence of the TR4 clone and what is the sequence of the T11 clone? These conflicts result in a lack of enablement of one of the T11 and TR4 compositions whichever one is not given by Figure 3.

In order to practice the α form of PDGF receptor the differentiation of the α form from the ß form is necessary. Note that this applies to claims directed to PDGF receptor that are not limited to a specific sequence. Without the sequence limitation the differentiation can only be practiced by comparison between the α and ß forms. If the comparison is to be done with antibodies, then these antibodies must be enabled. If the comparison is to be done with hybridization probes, then the α and ß form probe sequences must be enabled. It is noted that the enablement of sequences such as HB6, EF17, etc. as possible

probes is lacking. For example, the termini of these sequences are not clear as given in Figure 2. If the comparison is to be done via isoform binding, then a clear criteria between α and ß form isoform binding is required. The disclosure lacks enablement of any of the above methods of determination of the α form of PDGF receptor.

Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to compositions containing a DNA segment having the sequence of Figure 3. If other DNA segments are to be included in the scope of the claims, they must be enabled. See the following for the use of a deposit for the enablement of clones that may not be defined by the Figure 3 sequence. See M.P.E.P. §§ 706.03(n) and 706.03(z).

For DNA segments that are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the DNA segments are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the DNA segment or clone containing said DNA segment. The specification does not disclose a repeatable process to obtain both T11 and TR4 (note that the disclosure is unclear as to which clone is represented by Figure 3) and it is not apparent if the

clones are readily available to the public. If deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strains have been deposited under the Budapest Treaty and that the strains will be irrevocably and without restriction or condition released to the public upon issuance of a patent, would satisfy the deposit requirement made herein.

If the deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in MPEP 608.01(p)C, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;

(c) the deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposits will be replaced if they should ever become inviable.

Claims 1-7 are rejected under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What specifically are the compositions of T11 and TR4 that are being claimed? Note the above conflicts in the disclosure as to the T11 and TR4 sequences.

The metes and bounds of the "DNA segment" of claims 1-6 are undefined thus causing confusion as to what is being claimed. As worded, a whole chromosome is included in the scope of the claim. Is the intended "DNA segment" to include introns, only exons, promoters, only cDNA, or what?

Although the abbreviation "PDGF" is defined in the specification, such abbreviations can sometime also be used for other materials and thus may take on some unclarity as a result. The Examiner requests that applicants consider the replacement of such abbreviations in the claims with complete names for clarity.

The practice of the α form of the PDGF receptor is unclear as also summarized in the above enablement rejection. What is the clearly defined specific composition being claimed as the α form of PDGF receptor gene or protein? As an added concern, claim 7 is unclear in that the wording does not define whether the intent is to claim a receptor protein comprising versus consisting of the Figure 3 amino acid sequence.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent

therefore, subject to the conditions and requirements of this title".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1, 3, and 7 are rejected under 35 U.S.C. § 101

because the claimed invention is directed to non-statutory

subject matter. Specifically the claimed DNA segment and protein read on naturally occurring DNA and protein.

Claims 1, 3, and 7 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by either Gronwald et al. or Heldin et al.

The last six lines of the abstract of Gronwald et al. disclose the two forms of PDGF receptor via isoform binding data which reads on the α form of PDGF receptor DNA and protein instantly claimed. Similarly, Heldin et al. discloses binding studies which documents that both the α and the ß forms of the PDGF receptor gene and protein are disclosed as being contained in the fibroblasts used in the studies.

Claims 2 and 4-6 are rejected under 35 U.S.C. § 103 as being unpatentable over Gronwald et al.

The instant invention is directed to the composition whose critical content is the cloned α PDGF receptor DNA segment and its expression into the corresponding protein.

Gronwald et al. is discussed above as cloning the ß form of the PDGF receptor. Gronwald et al. goes on to disclose evidence for the other receptor type which reads on the α form. The disclosure of Gronwald et al. thus supplies motivation as well as the methodology to isolate the corresponding α form clone including expression of the α form into protein. Thus, absent a showing of unexpected results, it would have been obvious for someone of ordinary skill in the art at the time of the instant invention to prepare cloned α form PDGF receptor gene and

expressed protein.

Any inquiry concerning this communication should be directed to Ardin Marschel, Ph.D., at telephone number: (703) 308-0196.

AM

A. MARSCHEL:am

January 14, 1991

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
ART UNIT 187